3.2.A.3.S.3 CHARACTERIZATION – POLY(VINYLIDENE FLUORIDE-CO-HEXAFLUOROPROPYLENE) (PVDF-HFP)

3.2.A.3.S.3.1 Characterization of Structure and Physicochemical Properties of Poly(vinylidene fluoride-co-hexafluoropropylene)

The composition of PVDF to HFP, random distribution of HFP and VDF along the polymer back bone, crystallinity, thermal properties, and mechanical properties of the copolymer are described in this section.

Composition and Structure of Poly(vinylidene fluoride-co-hexafluoropropylene)
Poly(vinylidene fluoride-co-hexafluoropropylene) is a random copolymer composed of vinylidene fluoride (VDF) and hexafluoropropylene (HFP) monomers.

PVDF-HFP structure is shown below:

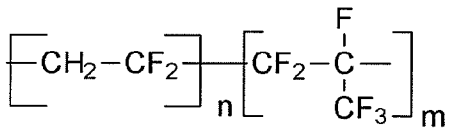
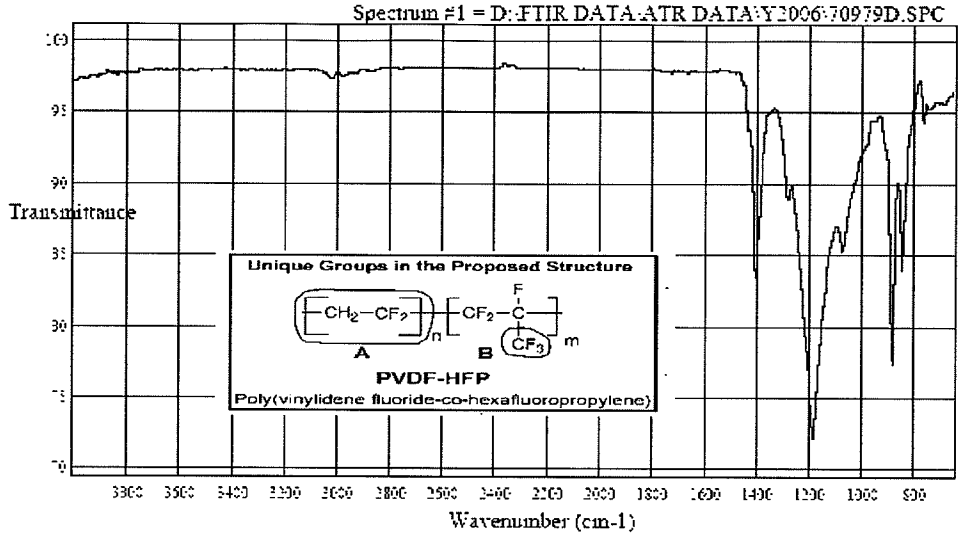


Figure 3.2.A.3.S.3-1 PVDF-HFP Structure

FTIR and Nuclear Magnetic Resonance (^{19}F NMR) studies have been used to confirm the structure of PVDF-HFP. Figure 3.2.A.3.S.3-2 shows FTIR spectrum of PVDF-HFP and the assignment of major bands.



PVDF-HFP (Poly(vinylidene fluoride–co-hexafluoropropylene), CAS [9011-17-0]

Group Identified in Proposed Structure	Functional Group in Proposed Structure	Assigned Functional Group Absorbance Region (cm^{-1})	Observed MIR Bands (cm^{-1})	Type of MIR Absorbance	Assigned Functional Group(s) from the MIR Spectrum	Ref.* Page
A	Polyfluorinated alkane	1360-1090 (s)	1176 (vs)	C-F stretch, a number of bands	Polyfluorinated alkane	199
	Aliphatic difluorinated compound, $-CH_2-CF_2-$,	(1250-1052 (vs)) 1300-1100 (s) 1200-1060 (s)	about 1270 (s) 1176 (vs)	(C-F stretch, two bands) C-F stretch, $-CF_2-$, asym C-F stretch, $-CF_2-$, sym	Aliphatic difluorinated compound, $-CH_2-CF_2-$,	199 200 200
		3095-2950 (m-w)	about 3020 (w)	C-H stretch, $-CH_2-$, asym frequency raised by electronegative groups		51, 200
		2995-2955 (m-w)	about 2930 (w)			51, 200
		near 1430	1399 (vs)	C-H stretch, $-CH_2-$, sym frequency raised by electronegative groups		
		990-800 (w)	876 (s)	C-H deformation, $-CH_2-$, stronger than expected $-CH_2-$, rocking		269 200
B	Hexafluoro-propene, $-CF_3$	1420-1205 (s-m) 1350-1120 (s-m)	1399 (vs) about 1270 (m)	C-F stretch, $-CF_3$, asym C-F stretch, $-CF_3$, sym	Hexafluoro-propene $-CF_3$	199 199

* Ref.: Infrared and Raman Characteristic Group Frequencies: Tables and Charts Third Edition. George Socrates, Wiley and Sons, 2001.

Proposed Functional Groups in the Molecule	Assigned Functional Groups in the Molecule
$-CH_2-CF_2-$, aliphatic difluorinated compound	$-CH_2-CF_2-$, aliphatic difluorinated compound
$-CF_3$, hexafluoropropene	$-CF_3$, hexafluoropropene

Figure 3.2.A.3.S.3-2 FTIR Spectrum of PVDF-HFP and the Assignment of Major Bands

Figure 3.2.A.3.S.3-3 shows the ^{19}F NMR spectra of PVDF–HFP (Solvay 21508) in Dimethylformamide - 7 deuterated (DMF - d7). The assignments of ^{19}F NMR chemical shifts for the different fluorocarbon groups are shown in the Table 3.2.A.3.S.3-1.

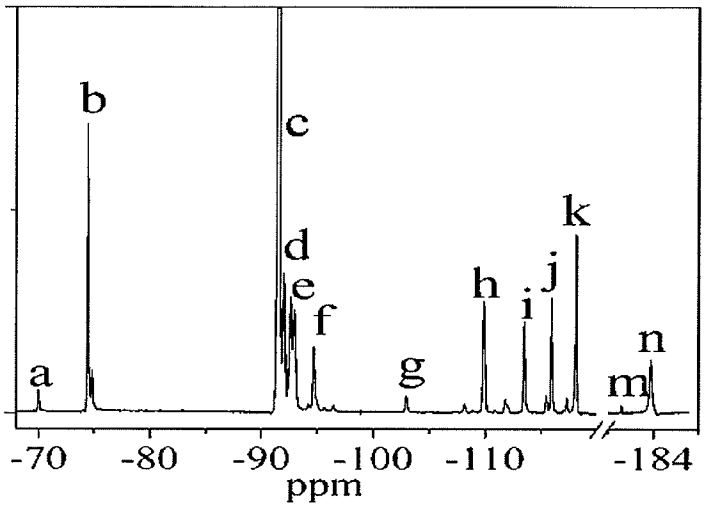


Figure 3.2.A.3.S.3-3 ^{19}F-NMR spectra of P(VDF-15%HFP) Copolymer in DMF - d7

Table 3.2.A.3.S.3-1 Assignments of the ^{19}F NMR chemical shifts observed for PVDF-HFP

Peak(s)	Assignment
a	-CH_2-CF_2-CF($C\underline{F}_3$)-CF_2-VDF
b	-CH_2-CF_2-CF_2-CF($C\underline{F}_3$)-CH_2-CF_2-
c	-CF_2-CH_2-$C\underline{F}_2$-CH_2-CF_2-
d	-$C\underline{F}_2$-CH_2-CF_2-CF_2-CH_2-CH_2-
e	-CH_2-CF_2-CF_2-CF(CF_3)-CH_2-$C\underline{F}_2$-
f	-CF_2-CH_2-$C\underline{F}_2$-CH_2-CH_2-CF_2-CF_2-
g	-CH_2-$C\underline{F}_2$-CF(CF_3)-CF_2-
h	-CH_2-$C\underline{F}_2$-CF_2-CF(CF_3)-
i	-CH_2-$C\underline{F}_2$-CF_2-CH_2-CH_2-
j	-CH_2-CF_2-$C\underline{F}_2$-CH_2-CH_2-
k	-CH_2-CF_2-$C\underline{F}_2$-CF(CF3)-
m	--CH_2-CF_2-C$\underline{F}$(CF_3)-CF_2-VDF
n	-CH_2-CF_2-CF_2-C$\underline{F}$(CF_3)-CH_2-CF_2

Both the content of hexafluropropylene (HFP) and the distribution of HFP in PVDF-HFP copolymers have been established from ^{19}F NMR studies. These studies have determined that the HFP content in Solvay grade 21508 is 15% w/w and that the HFP is randomly distributed along the polymer backbone.

Physical and Chemical Properties

General Properties

The polymer backbone of PVDF-HFP is composed entirely of carbon atoms, with 54% of the carbons bearing fluoro or trifluoromethyl groups, and the remaining 46% bearing hydrogen atoms. The high dissociation energy of the C-F bonds (540 kJ/mol) and the C-C bonds (370 - 406 KJ/mole) of the polymer backbone confer a high level of chemical stability to PVDF-HFP. The absence of reactive or enzymatically sensitive groups, such as anhydride, ester, amide, ether, ketone, aldehyde, carbonate, or phosphate bonds makes the polymer resistant to hydrolytic, oxidative, or enzymatic cleavage. The polymer is thermally stable up to 340°C.

Crystal Structure and Crystallinity

The PVDF-HFP copolymers have lower crystallinity than the PVDF homopolymer due to the incorporation of the HFP monomer, which contains pendant CF_3 groups (Solvay's Technical Publications). Due to the free radical polymerization process, the CF_3 groups are atactic. Hence, they are oriented randomly along either side of the polymer backbone. The HFP monomer side group (CF_3) is bulky, thereby introducing steric hindrance to the chain conformation of the polymer, and reducing the degree of crystallinity. The lower level of crystallinity results in good elongation properties, while maintaining a useful level of polymer hardness in order to withstand crimping and other mechanical stresses placed upon the coating during its manufacture and use.

The crystalline region in PVDF- HFP can be composed of multiple crystal phases, e.g. alpha, beta, gamma, etc. Since the crystal melting points for all the crystal phases are around 133°C, the conversion from one crystalline phase to another in both the raw material and XIENCE™ V product will not occur under any normal manufacture and storage conditions.

The XIENCE™ V EECS formulation and coating is performed with a multi-solvent system, acetone and cyclohexanone. When dissolved, any crystal structure of the PVDF-HFP raw material is removed. Upon coating, and drying, the PVDF-HFP polymer then crystallizes to its equilibrium level as it forms the drug reservoir matrix. The crystallization of PVDF-HFP after stent coating is facile due to its low Tg of –29°C and supported by the fact that the coating baking temperature of 50°C and the EtO sterilization temperature of 40°C lie above this Tg, but below the melting point of 133°C.

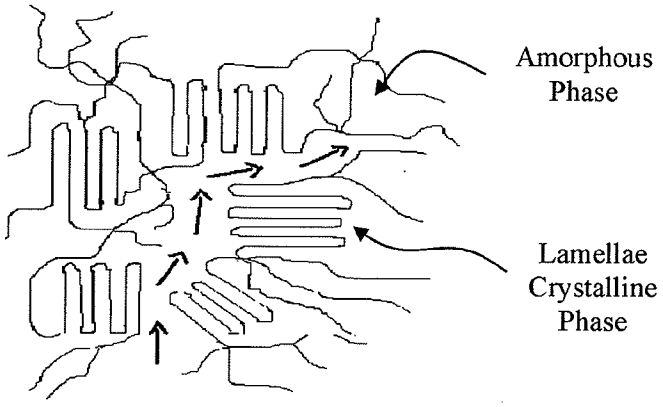


Figure 3.2.A.3.S.3-4 Schematic Structural Model for PVDF-HFP and Drug Transport

The above figure is a schematic representation of drug diffusing through the free volume in the amorphous phase of the semi-crystalline polymer. It is this amorphous property of the polymer, not the crystal structure that is important for drug release. The characteristics of PVDF-HFP morphology are discussed below, and the drug-polymer interaction has been investigated with several techniques which are summarized in Section 3.2.P.2.1.2 Excipients

Thermal Properties of PVDF-HFP

The thermal properties of three lots of PVDF-HFP used in the manufacturing of XIENCE™ V have been characterized at Abbott Vascular. These thermal properties of PVDF-HFP are listed in Section 3.2.A.3.S.1.3, PVDF-HFP General Information General Properties. The thermal properties of the polymer in bulk, and polymer coated stents, are presented in the following sections.

Properties of Bulk PVDF-HFP Polymer

As supplied, PVDF-HFP containing 85% VDF and 15% HFP (w/w) has a melting temperature (T_m) of 133°C and a heat of fusion (ΔH_f) of 22.5 J/g. The heat of fusion of the copolymer is dependent on polymer crystallinity and would vary with different ratios of HFP to VDF monomers. The HFP monomer strongly disrupts the formation of crystalline regions of the polymer and lowers both the melting temperature and the heat of fusion compared to the homopolymer (Table 3.2.A.3.S.3-2).

Table 3.2.A.3.S.3-2 Thermal properties of PVDF and PVDF-HFP*

Polymer	HFP content (wt %)	T_m (°C)	ΔH_f (J/g)
Solvay PVDF homopolymer (All grades)	0	172 - 176	56 - 64
Solvay 21508 PVDF-HFP	15	133	22.5

*Solvay's Technical Publication

The lower heat of fusion of the 15% HFP copolymer compared to the homopolymer is evident in the above table, and is a measure of the lower degree of crystallinity. Comparing these heats of fusion to that from the literature for perfectly crystalline PVDF (104.7 J/gm) indicates that the degree of crystallinity of PVDF-HFP is approximately 25% compared to that of the homopolymer of 57%. This lower degree of crystallinity of the PVDF-HFP copolymer increases the drug permeability compared to the homopolymer and results in solubility properties which are compatible with the manufacturing process of XIENCE™ V. Therefore, it is critical to control the VDF-to-HFP composition.

The heat of fusion of PVDF-HFP pellets were evaluated by Differential Scanning Calorimetry (DSC) at Abbott Vascular. The heat of fusion for sliced pellets from three lots is listed in Table 3.2.A.3.S-6. The average heat of fusion and melting temperature for PVDF-HFP was 23.9 J/g and 133°C.

Table 3.2.A.3.S.3-3 Heat of Fusion and Melting Temperatures of Bulk PVDF-HFP

Lot #	ΔH_f (J/g) (n = 2)	Tm [°C] (n = 2)
99352755	23.4 ± 0.7	133.5 ± 0.7
99352760	22.5 ± 1.4	133.5 ± 0.7
99403977	25.7 ± 1.1	131.5 ± 0.7

Spray-Coated Samples

Polymer only coated stents were spray coated from acetone and cyclohexanone (70:30 (w/w)) solutions using a process comparable to the commercial XIENCE™ V process.

Table 3.2.A.3.S.3-4 Heat of Fusion and Melting Temperatures of Spray Coated Polymer

Stent Lot #	ΔH_f (J/g) (n = 6)	Tm [° C] (n = 6)
51004E1	27.5 ± 1.6	131.3 ± 0.5

Compared to the polymer as received, the greater heat of fusion for the polymer only coated stents is partly due to the greater degree of crystallinity from the annealing process associated with solvent drying. As received, the polymer is quenched from the melt, and therefore, not fully annealed. The melting point is very close to that of the received polymer indicating the crystal structure formed is the same.

Mechanical Properties

The tensile and elongation properties of PVDF-HFP are listed in section 3.2A.3.S.1.3, PVDF-HFP General Information General Properties. Solvay Solexis's product data sheet shows that the polymer is highly flexible. Specifically, it can elongate 600% more than its original length, which is well above the maximum deformation the coating is subjected to during stent crimping and expansion. This polymer has a hardness of Shore

D 60 (at 2 mm thickness), which allows the coating to be strong enough to tolerate mechanical challenges during the stent processing. The microstructure of the polymer on the stent has been characterized and presented in section 7.5, Product Testing.

3.2.A.3.S.3.2 Impurities in PVDF-HFP

PVDF-HFP polymer is polymerized by aqueous suspension polymerization at elevated temperature and pressure at Solvay Solexis. No suspension agent is used in the reaction. The monomers are gases under ambient conditions. The unreacted monomers and initiator decomposition products are removed during the degassing step after polymerization. The polymers are further purified with purified water to remove remaining peroxide initiator or initiator decomposition products. No other additives are added during the polymerization, purification, or pelletization steps. Consequently, the Solvay PVDF homopolymers and copolymers are extremely pure and metal levels are in the parts per billion range. PVDF homopolymer is the recommended material used for the distribution of ultra pure water and other chemically pure fluids in semiconductor fabrication plants. The virtual absence of contaminants, leachables and chemical inertness makes it ideal for the industry applications required high purity and stability[1]

Possible impurities from the manufacturing process could be water, peroxide initiator, initiator breakdown products or contaminants from manufacture equipment. The following study demonstrates that the polymer is highly pure and contains no or minimal impurities.

Extractables Study of PVDF-HFP
Abbott Vascular has conducted extraction studies on multiple lots of PVDF-HFP to detect impurities, and to confirm the claims of high purity by Solvay Solexis. The extractions were done with the polymer highly swollen, but not fully dissolved, to avoid significant polymer interferences. High Performance Liquid Chromatography (HPLC) was used to investigate and identify any impurities and/or ascertain the levels of any detected unidentified impurities that may have been present.

Two solvents, acetonitrile and isopropyl acetate, were used in the extraction study. PVDF-HFP partially dissolves and swells in Acetonitrile. Isopropyl acetate swells PVDF-HFP. The presence of possible peroxide initiator such as benzoyl peroxide and its degradation products in PVDF-HFP was investigated. All unknown peaks if detected were investigated as well.

In the isopropyl acetate extraction study, PVDF-HFP polymer was extracted with isopropyl acetate (IPAc) at room temperature. The residue was solubilized in acetonotrile and analyzed by HPLC with UV-Vis detection at 226 nm, 238 nm and 254 nm. No impurities were observed in HPLC analysis at the detection limit of approximately 3 ppm.

[1] Fluropolymers, A Rapra Industry Analysis report, April 2001; Purely the best Solef® HP PVDF, Technical Publications, Solvay Solexis

In the acetonitrile extraction study, PVDF-HFP polymer was extracted with acetonitrile at room temperature. The extractant was analyzed by HPLC with UV-Vis detection at 226 nm, 238 nm and 254 nm. The method was calibrated for benzoyl peroxide, and its breakdown products such as benzoic acid and benzene. At a detection limit of approximately 3 ppm, no benzoyl peroxide or its degradation products were detected in the polymer. However, two minor unknown peaks were occasionally observed at a level of < 5 ppm, as quantified by HPLC with evaporative light scattering detection (ELSD).

The polymer was tested for potential water and low molecular weight oligomers by thermal gravimetric analysis. Batch analysis data presented in section 3.2.A.3.S.4.4, PVDF-HFP Batch Analyses of PVDF-HFP show very low levels of volatiles.

Water Extractable Impurities Study on Polymer Coated Stents
An extractables study was performed on polymer coated stents. Table 3.2.A.3.S.3-5 provides the study matrix.

Table 3.2.A.3.S.3-5 Test Stent Configuration

Test Group	Primer Polymer	Matrix Polymer	Primer/matrix polymers
Polymer	PBMA	PVDF-HFP	PBMA and PVDF-HFP
Polymer load	3x standard primer weight	3x standard matrix weight	3x standard primer weight 3x standard matrix weight
# of stents used in the extraction	100	100	100

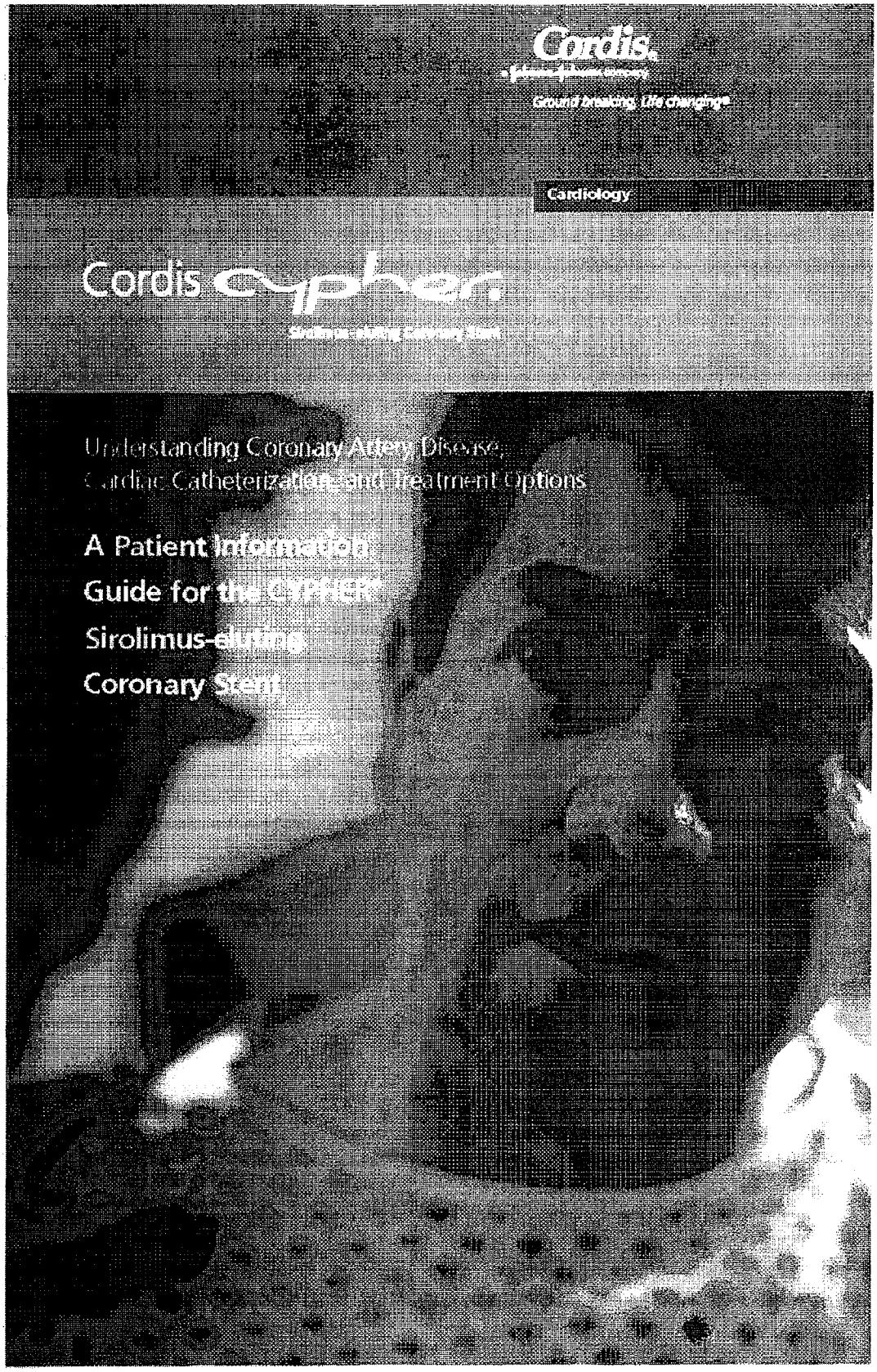
Purified PBMA was used in the study. The stents used were 4.0 x 28 mm polymer only (PBMA and PVDF-HFP) coated stents. After spray coating and oven drying, the stents were placed in clean amber vials. One hundred sample units were taken from each group (Primer group, matrix polymer group, and primer/matrix polymer group). They were extracted with 60 mL of purified water (per Japan Pharmacopoeia) at 70 ± 2°C for 24 hours. A purified water control was extracted in identical containers. The following tests were performed on the extracts. Table 3.2.A.3.S.3-6 summarizes the test results.

- Visual appearance
- pH determination
- Heavy metals
- Potassium permanganate oxidation test
- UV absorption
- Non-volatile residual

Table 3.2.A.3.S.3-6 Polymer Extraction Test Results

Tests	Acceptance Criteria	Primer (PBMA) coated stents	PVDF-HFP coated stents	Primer/ PVDF-HFP coated stents
Visual appearance	Extract be colorless, transparent and has no impurity	Pass	Pass	Pass
pH	pH difference between test solution and blank < 1.5	< 0.5	< 0.5	< 0.5
Heavy metal	Per Japanese Pharmacopoeia 14th amendment, Part 1. The color of the test solution is no more dense (dark) than blank solution with lead solution treatment.	Pass	Pass	Pass
$KMnO_4$ oxidation test	Difference in consumption rate of 2 mM $KMnO_4$ is less than 1.5 mL	< 0.5 mL	< 0.5 mL	< 0.5 mL
UV absorption	Absorbance < 0.20 when measured in wavelength at 220-350 nm	< 0.01	< 0.01	< 0.02
Non-volatile residual	Non-volatile residual < 1.0 mg after evaporation to dryness of 10 mL extract solution	< 1.0 mg	< 1.0 mg	< 1.0 mg

All three groups of stents met requirements.


Cordis
Ground breaking. Life changing.
Cardiology
Cordis cypher
Understanding Coronary Artery Disease,
Cardiac Catheterization and Treatment Options
A Patient Information
Guide for the CYPHER
Sirolimus-eluting
Coronary Stent

Patient's
Name _____

Instructions:

Introduction

You have an important role to play in order to ensure that your procedure will be successful. Thoroughly read this booklet, cooperate with your physician and follow through with your responsibilities as part of the patient/medical team.

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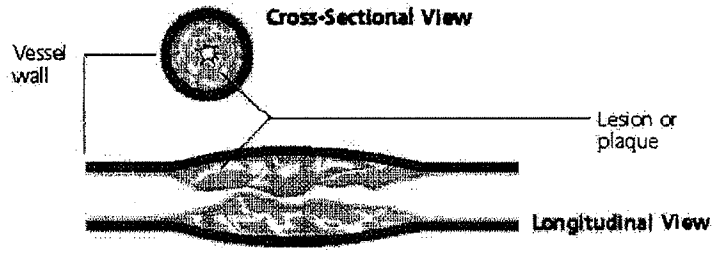
Coronary Artery Disease

If you or a member of your family has been diagnosed with coronary artery disease (CAD), you may have questions about the disease and its treatment, especially if your doctor has recommended angioplasty followed by implantation of a drug-eluting coronary stent. This booklet answers some of the questions patients with coronary artery disease often ask.

- Angioplasty - A balloon procedure to open an obstruction or narrowing of a blood vessel. Also known as percutaneous transluminal coronary angioplasty (PTCA).

- Stent - An expandable, slotted metal tube, inserted into a vessel. A stent acts as a scaffold to provide structural support for a vessel. A drug-*eluting* stent allows for the active release of that particular drug at the stent implantation site.



Plaque partially blocking artery

What Causes Coronary Artery Disease?

The heart is a muscle that acts like a pump to move blood throughout the body. To function properly, the heart must receive oxygen. Oxygen is supplied to the heart by the coronary (heart) arteries that wrap around the surface of the heart. When coronary artery disease (CAD) is present, blood flow through the arteries can be reduced. When this happens, the heart muscle may not receive enough oxygen, and chest pain (called angina) may be felt.

CAD is caused by the build-up of fatty substances, such as cholesterol, that collect along the lining of the coronary arteries, in a process known as atherosclerosis. You may hear this referred to as a "plaque," "lesion," "blockage" or "stenosis." This means that there is a narrowing in the artery caused by a build-up of substances which may eventually block the flow of blood. Because the coronary arteries supply oxygen-rich blood to the heart, untreated blockages can be very serious and can lead to a heart attack (myocardial infarction) or even death. Over the course of a person's lifetime many influences can cause one or more of your coronary arteries to become narrowed or blocked.

Note: The underlined words throughout this patient guide are referenced to definitions at the bottom of the respective page.

Atherosclerosis A disease process in which fatty substances (plaque), such as cholesterol, are deposited on the inner lining of blood vessels.

Angina (Pectoris) Chest discomfort, pain, tightness or pressure. May also have associated pain in neck, jaw, back or arm. May include profuse sweating, nausea, or shortness of breath. Angina may be a single symptom or a combination of these symptoms.

Coronary Arteries The coronary arteries are special blood vessels which supply the heart with necessary oxygen and nutrients. The heart does not function properly without enough oxygen.

Coronary Artery Disease Atherosclerosis of the coronary arteries.

Myocardial Infarction Commonly called a "heart attack." Involves irreversible damage to heart tissue/muscle. Insufficient oxygen reaching the heart muscle via the coronary arteries may cause angina, heart attack (myocardial infarction), or even death to the affected area of the heart.

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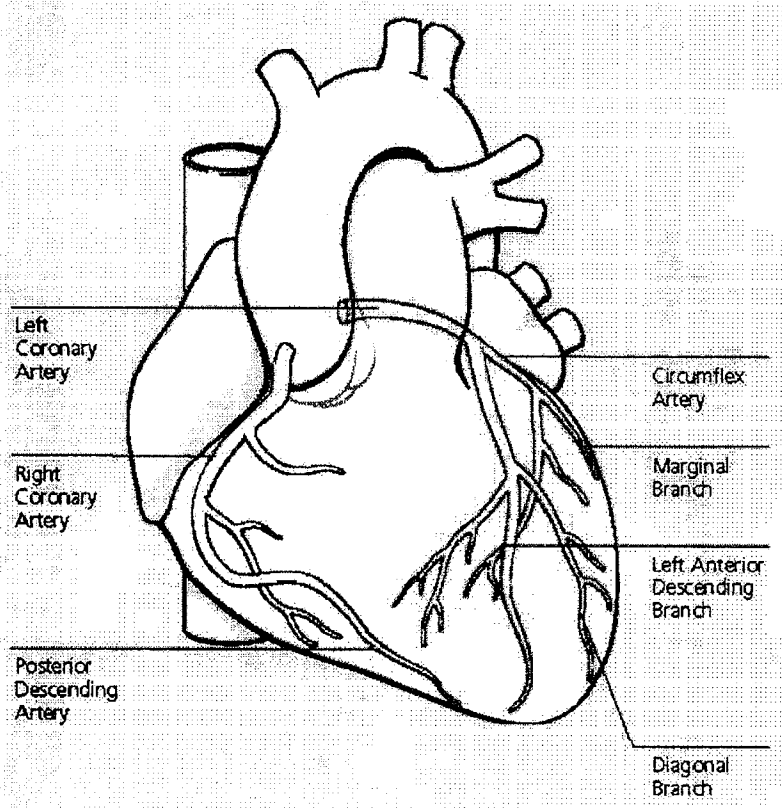
The Heart and Its Coronary Arteries



Symptoms of Heart Disease

Coronary artery disease can progress very slowly, often without symptoms. Most people do not realize that they have heart disease. In fact, the first sign that something may be wrong could be an episode of angina, or even a heart attack. Typical angina symptoms are feelings of pressure, tightness, or pain in the chest, arm, back, neck or jaw. Symptoms also include heartburn, nausea, vomiting, excessive sweating, fatigue or shortness of breath. Angina may occur as only one or many of these symptoms.

Although the exact cause of CAD is not known, there are certain risk factors that are often seen in patients with coronary artery disease. These factors include: high blood pressure, having a close relative with heart disease, high cholesterol and/or triglycerides in your blood, diabetes, smoking, excessive weight, and lack of a regular exercise program. Males are more likely to develop coronary artery disease than females. In addition, menopausal status in women may play a role in coronary artery disease.

Risk Factors for CAD

You are at greatest risk for CAD if you:

- have high blood pressure
- are diabetic
- smoke cigarettes
- are overweight and/or inactive
- have a relative with the disease

Cholesterol A substance that circulates in the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fats

Diabetes A disease affecting one's metabolism of glucose (sugar) which causes changes in blood vessels. These changes may aid in the development of coronary artery disease

Triglycerides Substances in the blood that are a component of the "bad" type of cholesterol

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How is Heart Disease Diagnosed?

You may have experienced symptoms of heart disease which caused you to seek your doctor's attention. If you have experienced symptoms or have an increased risk of heart disease, your doctor may recommend that you have an exercise stress test, an electrocardiogram (EKG), chest x-ray, and blood tests. Stress tests measure changes in the electrical activity of your heart as you perform controlled exercise, and may show if heart muscle is at risk of dying or if there has been damage to your heart. These results may indicate a need for further testing. Your doctor may then recommend a cardiac catheterization or coronary angiogram. It is one of the most useful methods to diagnose coronary artery disease because it allows the doctor, under x-ray, to see exactly where the coronary arteries are narrowed or blocked.

- Cardiac - Relating to the heart.
- Catheterization - A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.
- Coronary Angiogram - A test used to diagnose CAD using the catheterization procedure. Contrast dye is injected into the coronary arteries via a catheter, and this allows the doctor to see, on an x-ray screen, the exact site where the artery is narrowed or blocked.

Catheter A tube used for gaining access to one of the body's cavities or blood vessels. In angioplasty, a catheter provides access to the heart's arteries.

Electrocardiogram (EKG) A test that measures and shows the electrical activity of the heart muscle.

Stress Test A test that measures electrical changes in the patient's heart (EKG) while the patient is doing controlled exercise. The stress test can show if there has been damage to the heart or if there is decreased blood flow to areas of the heart.

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Cardiac Catheterization

Cardiac catheterization is performed in a specialized area in the hospital called a Cardiac Catheterization Laboratory. The night prior to the test, you may not be allowed to eat or drink anything after midnight. Before the catheterization, a doctor will explain the procedure to you and ask certain questions about your health. While you are discussing this test, you should ask any questions or mention any concerns or worries that you have about the procedure. After the procedure has been explained, you will be asked to sign a consent form, which gives your permission for the test to be performed.

Before your procedure begins, you will be taken to the room where the cardiac catheterization will be done. Your heart rhythm will be monitored and an intravenous line (IV) will be placed to provide you with fluids and to make it easier to administer any needed medication.

Your arm or groin will be shaved and cleaned with an antiseptic solution and sterile drapes will be placed in this area. Before the procedure begins, you will receive local anesthetic to numb the area. You may feel some pressure and a burning sensation at the site, but it will only last a few seconds.

During the procedure you will not need general anesthesia, but a sedative may be given to help you relax. It is important for you to remain awake so that you can move or breathe deeply when asked to do so by the doctor. Following these instructions may improve the quality of the x-ray pictures.

During this procedure a long tube called a catheter is placed through another small tube, (called a catheter sheath introducer) that is inserted in your arm or groin. The catheter is guided to your heart and then into the opening of the arteries. The catheter provides a pathway for a special liquid dye to flow into the arteries. This liquid dye allows the doctor to see the shape and size of your arteries as well as the function of your heart muscle on an x-ray screen.

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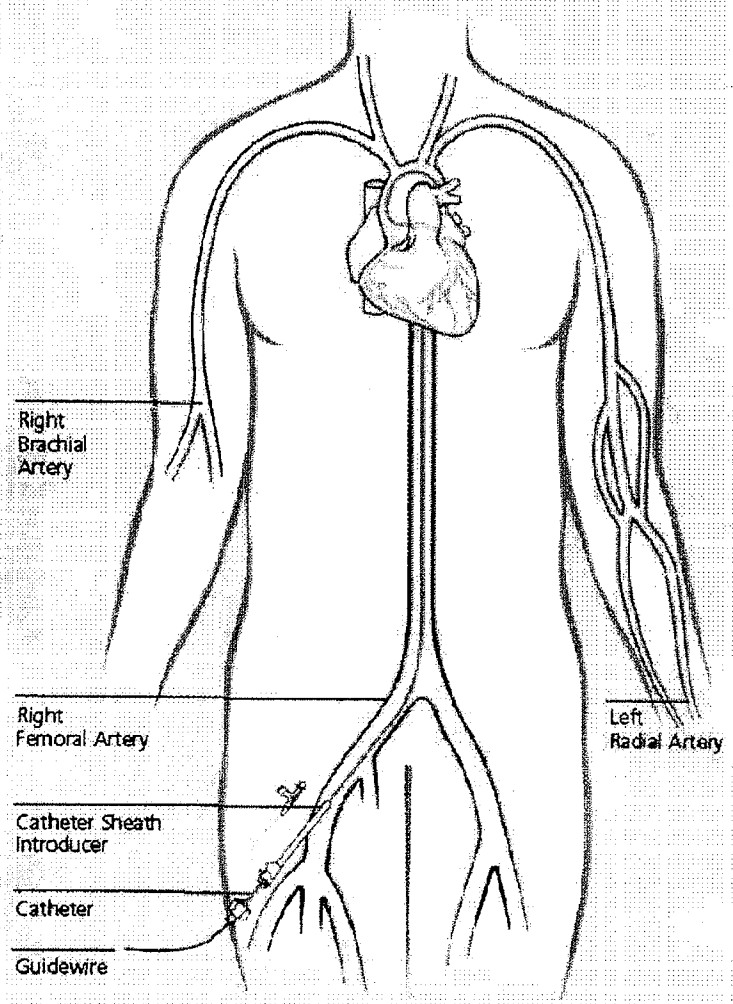
In coronary angiography, a catheter is inserted into an artery and then guided to your heart.



Once the catheter is positioned, the doctor will take pictures of your heart. With the catheter in the main pumping chamber of the heart (left ventricle), some dye will be injected through the catheter and a picture will be taken. The dye makes it easier for the doctor to see the shape and overall function of your heart. You may be asked to take a deep breath and hold it, which allows the doctor to have a clearer view of your heart on the x-ray screen. You may also feel a hot flush when the dye is injected. This feeling is to be expected and normally passes in 15 to 30 seconds.

Pictures will also be taken of your coronary arteries from several different angles. Once all these pictures have been developed and your doctor has been able to review them, he or she will be able to discuss the final results with you. If the cardiac catheterization showed that there were one or more blockages in your coronary arteries, then further treatment may be recommended.

Can Heart Disease Be Treated?

Most patients with heart disease receive medication to help prevent a heart attack, and doctors usually recommend controlled exercise and a low-fat diet. Medication may also be prescribed to help lower cholesterol levels in the blood. However, there are no drugs available to eliminate blockages within the heart arteries. If heart disease is present, you may be at risk of having a heart attack if the disease is not treated. Until several years ago, the only treatment for blockages of heart arteries was Coronary Artery Bypass Graft (CABG) surgery.

Today, there are several options available to you. Your doctor can discuss these with you to determine which option is best for you.

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Balloon Angioplasty

This procedure may be done immediately following your catheterization or you may be sent home and instructed to return for the procedure. You will be asked not to eat or drink anything after midnight on the night before your procedure. It is important that you follow these and any other instructions carefully.

If you have had a cardiac catheterization procedure, angioplasty is similar in many ways. Your heart rhythm will be monitored, an intravenous line will be inserted in your arm, your arm or groin area will be shaved and cleaned and the procedure will be performed through that area. As with cardiac catheterization, it is important for you to follow your doctor's instructions during the procedure.

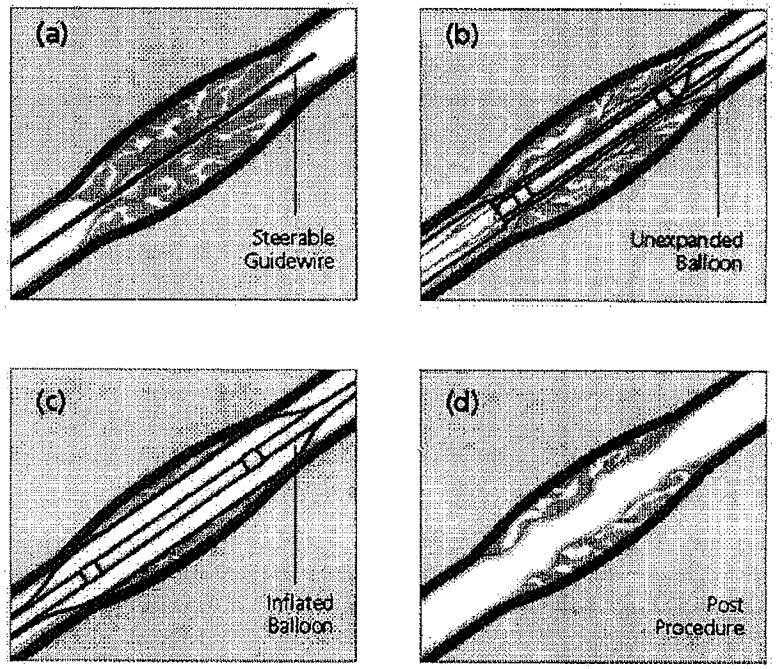
Balloon Angioplasty Step-by-Step

- After local anesthetic is given, a small incision is made in your arm or groin and a catheter sheath introducer is inserted into the artery. Then, a narrower and longer tube, called a guiding catheter, is passed through the sheath to the heart.
- Contrast dye (x-ray dye) is injected through the guiding catheter to allow the doctor to see the arteries of your heart on an x-ray machine called a fluoroscope.
- While observing the arteries on the x-ray screen, (a) the doctor threads a guidewire through the guiding catheter and advances it to the diseased artery.
- A balloon catheter is inserted over the guidewire (b) and positioned at the site of the blockage.
- Once the balloon catheter is in place, the balloon is expanded (c). As the balloon expands, it compresses the fatty deposits (plaque) against the lining of the artery. The balloon may be expanded one or more times before it is removed. X-ray pictures are taken so that the doctor can monitor your artery as the blood flow is improved.

- Once the balloon catheter is removed, the fatty deposits remain compressed, and blood flow is restored to your heart (d). The balloon procedure may last from 30 to 90 minutes, but varies from patient to patient.

It is not uncommon to experience some discomfort or a pressure sensation in your chest when the balloon is inflated. During the procedure you will be asked to remain very still. You will be asked how you are feeling; be sure to let your doctor know if you experience any discomfort.

Balloon Angioplasty of partially blocked artery.



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Coronary Artery Re-narrowing May Occur After Balloon Angioplasty

It is not uncommon for patients to develop a re-narrowing in the same site as the initial balloon procedure. In fact, one-third to one-half of patients who have successful balloon angioplasty will return in the first 4-6 months after the balloon procedure. This kind of narrowing is called "restenosis" and is due to a type of scar tissue formation.

In order to lower the risk for restenosis, your doctor may recommend a procedure called coronary stent implantation. Experience has shown that use of a coronary balloon-expandable stent reduces the rate of restenosis and improves the success rate of balloon angioplasty.

What is a Coronary Artery Stent?

A coronary stent is a small, slotted, metal tube that is mounted on a balloon catheter. It is inserted into your artery after a wider channel has been created by a balloon, and is positioned at the site of the blockage. When the balloon is inflated, the stent expands and is pressed into the inner wall of the artery. The balloon is then deflated and removed with the stent remaining in place. The stent acts as a scaffold that helps to hold the artery open, which improves blood flow and relieves symptoms caused by the blockage.

Magnetic Resonance Imaging (MRI) A diagnostic study similar to a CT or CAT scan which creates an image using electromagnetic waves instead of x-ray

Restenosis A re-narrowing or blockage of an artery at the same site where angioplasty was previously done

Tesla A unit measure of magnetic strength

A stent is a permanent implant that remains in your artery. Over the next weeks, your cells will form a natural covering that will hold the stent securely in place. Persons allergic to 316L stainless steel, polymers (plastics) or sirolimus may suffer an allergic response to this implant. It is important to notify your physician if you have any known metal, plastic or drug allergies. Magnetic Resonance Imaging (MRI) of single or two overlapping CYPHER® Sirolimus-eluting Coronary Stents has been shown to be safe in MRI units with a magnetic strength of three Tesla or less. Metal detectors found in airports and appliances such as microwave ovens also will not affect the stent or make it move.

Some of the currently available stents are:

- Uncoated stents - An expandable, slotted metal tube that acts as a mechanical scaffold in a vessel. The BX VELOCITY® Stent is an example of an uncoated stent.
- Coated stents - A stent with a thin surface covering.
- Drug-eluting stents - The CYPHER® Stent is an example of a drug-eluting stent. The CYPHER® Stent contains a drug called sirolimus. A drug-eluting stent allows for the release of that particular drug at the stent implantation site. The action of the drug (sirolimus) is intended to limit the over-growth of normal tissue as the healing process occurs following coronary stent implantation.

How is a Coronary Stent Implanted?

A coronary stent may be placed after the initial balloon procedure, which is done to create a wider opening for the stent. You will have the same feelings when the stent is put in place as when the balloon was expanded during the procedure.

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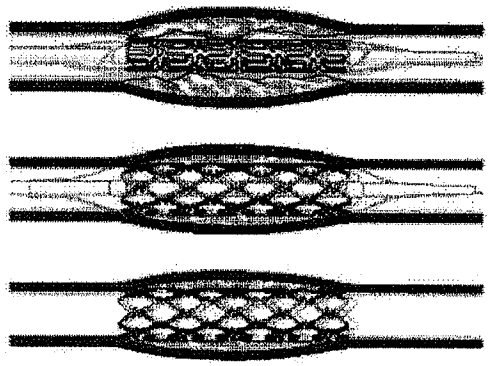


- The stent, which is mounted on a balloon catheter, is inserted into the artery and placed at the site of the initial blockage.
- When the balloon and stent are positioned, the balloon is inflated. The stent expands and becomes firmly pressed into the inner wall of the artery. One or more stents may be used at the site that was narrowed or blocked.
- X-ray pictures are taken so that the doctor can see the stent in your artery. Additional balloon inflations may be needed to fully expand the stent.
- The balloon catheter is deflated and removed along with the guidewire and guiding catheter.
- The stent will remain in place permanently.

Coronary Stent Re-narrowing (In-stent Restenosis) May Occur After Coronary Stenting

Occasionally some patients develop a re-narrowing within the stent which may lead to recurrence of symptoms such as feelings of pressure, tightness, or pain in the chest, arm, back, neck or jaw (see also "Symptoms of Heart Disease"). This kind of narrowing is called "in-stent restenosis" and is due to a type of scar tissue formation.

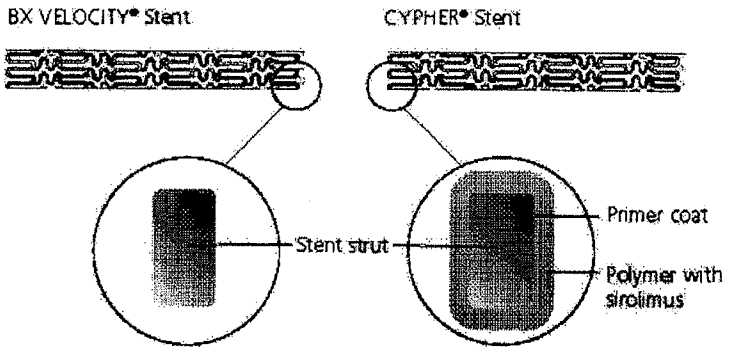
In fact, 10 to 20 percent of patients who have successful stent implantation develop in-stent restenosis over a period of 4-6 months.

To lower the risk of in-stent restenosis, your doctor may recommend implantation of a CYPHER® Stent. Experience has shown that use of the CYPHER® Stent can reduce the rate of in-stent restenosis and repeat cardiac intervention.

What is the CYPHER® Sirolimus-eluting Coronary Stent and How Does It Work?

The CYPHER® Stent is designed to prevent re-narrowing from occurring within the stent (in-stent restenosis). It consists of a stainless steel BX VELOCITY® Stent with a thin coating of drug (sirolimus) on its surfaces. The drug is located within a polymer (plastic) coating. The BX VELOCITY® Stent is designed to provide mechanical support in the artery, while the drug (sirolimus) is slowly released into the artery wall around the stent. The action of the drug (sirolimus) is intended to limit the overgrowth of normal tissue as the healing process occurs following coronary stent implantation. Overgrowth of normal tissue is thought to be a major factor responsible for re-narrowing of the artery after stenting.

Cross-sectional view of a coated stent to show how coating conforms to the surface of the bare metal stent



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When Should the CYPHER® Stent Not Be Used (Contraindications)?

- If you cannot take aspirin or blood-thinning medications (also called antiplatelets or anticoagulants).
- If you are unwilling or unlikely to comply with antiplatelet or anticoagulant therapy.
- If you cannot receive recommended antiplatelet and/or anticoagulation therapy.
- If you have an allergy to the drug sirolimus, structurally-related drugs or a certain category of polymers known as polymethacrylates or polyolefin.
- If the physician decided that the blockage will not allow complete inflation of the angioplasty balloon or proper placement of the stent or delivery balloon.

What Are the Risks and Potential Benefits of Treatment with the CYPHER® Sirolimus-eluting Coronary Stent?

Potential adverse events which may be associated with the implantation of a coronary stent include: allergic reaction, irregular heart rhythm, death, drug reactions to blood-thinning agents (antiplatelet/anticoagulants) or contrast media, emergency bypass surgery, fever, bleeding at the puncture site, chest pain or angina and stroke.

Potential adverse events related to the drug sirolimus (based on studies of patients who used the drug for a prolonged period of time) include: infection, tumor formation, fatigue, joint pain and diarrhea.

Exposure to sirolimus and the polymer coating is directly related to the number of implanted stents. Use of more than two CYPHER® Stents has not been adequately evaluated. Use of more than two CYPHER® Stents will result in your exposure to a larger amount of sirolimus and polymer coating than experienced in the clinical studies.

There is no clinical experience on the performance of the CYPHER® Stent before or after use of brachytherapy.

The safety and effectiveness of the CYPHER® Stent was compared to BX VELOCITY® Stent (an uncoated stent) in the SIRIUS study that included 1058 patients. All patients were followed for one year. The study results showed that patients who received a CYPHER® Stent had a significantly lower incidence of repeat procedures when compared to the uncoated BX VELOCITY® Stent group. Additionally, patients treated with the CYPHER® Stent had an in-lesion restenosis rate of 8.9% while patients treated with the BX VELOCITY® Stent had an in-lesion restenosis rate of 36.3%. The combined occurrence of death, heart attacks, bypass surgery and repeat angioplasty was 8.4% for CYPHER® Stent patients and 22.9% for BX VELOCITY® Stent patients. For patients treated with the CYPHER® Stent in indications not studied in this clinical trial, clinical results may vary.

The study showed that the risks associated with the CYPHER® Stent are equivalent to the risks associated with the BX VELOCITY® (uncoated) Stent.

Late-term risks and benefits (i.e., greater than five years) associated with the CYPHER® Stent are presently unknown but are currently under investigation.

Potential adverse events associated with coronary stent placement	
• Allergic reaction • Aneurysm • Arrhythmias • Cardiac tamponade • Death • Dissection • Drug reactions to antiplatelet agents/ anticoagulation agents/contrast media • Emboli, distal (tissue, air, or thrombotic emboli) • Embolization, stent • Emergency CABG • Failure to deliver the stent to the intended site • Fever • Fistulization • Hemorrhage • Hypotension/Hypertension	• Incomplete stent apposition • Infection and pain at the intended site • Myocardial infarction • Myocardial ischemia • Occlusion • Prolonged angina • Pseudoaneurysm • Renal failure • Restenosis of stented segment (greater than 50% obstruction) • Rupture of native and bypass graft • Stent migration • Stroke • Thrombosis (acute, subacute, late, or very late) in the stent • Ventricular fibrillation • Vessel spasm • Vessel perforation
Potential adverse events related to Sirolimus (following prolonged oral use)	
• Abnormal liver function tests • Anemia • Arthralgias • Diarrhea • Hypercholesterolemia • Hypersensitivity, including anaphylactic/ anaphylactoid type reactions	• Hypertriglyceridemia • Hypokalemia • Infections • Interstitial lung disease • Leukopenia • Lymphoma and other malignancies • Thrombocytopenia

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Other Treatment Options

Other treatment options include balloon angioplasty, placement of other stents or bypass surgery.

- Balloon angioplasty - See "Balloon Angioplasty" section. This may include the use of an angioplasty catheter or other devices that are intended to open the obstruction or narrowing of the blood vessel.
- Uncoated stents - An expandable, slotted metal tube that acts as a mechanical scaffold in a vessel. The BX VELOCITY® Stent is an example of an uncoated stent.
- Coated stents - A stent with a thin surface covering.
- Bypass surgery - An operation in which a piece of vein or artery is used to bypass a blockage in a coronary artery.

Preparation for a CYPHER® Sirolimus-eluting Coronary Stent

If you know in advance that you will be receiving a CYPHER® Stent, your doctor will ask you to follow certain instructions. For several days before the procedure, you may be asked to take aspirin and other prescribed medications.

Caution. Be sure to let your doctor know:

- If you are taking any other medications
- If you have a history of bleeding problems
- If you have any metal allergies (i.e., 316L stainless steel)
- If you are allergic to the drug Rapamune[1] (sirolimus), its derivatives or a certain category of polymers known as polymethacrylates or polyolefin
- If you are currently taking Rapamune
- If you are currently or think you may be pregnant

- If you are currently nursing
- If a dental or surgical procedure is scheduled to follow your CYPHER® Stent procedure while on antiplatelet medication

Note: Sirolimus is also available in tablet and liquid form, known by the name Rapamune. Let your doctor know if you are currently using this drug.

How is Treatment with the CYPHER® Sirolimus-eluting Coronary Stent Performed?

Placement of a CYPHER® Stent is no different from the placement of an uncoated stent, described earlier in this booklet. You will be brought to the cardiac catheterization laboratory and prepared for your heart catheterization. The CYPHER® Stent will be placed after the initial balloon procedure, which is done to create a wider opening for the stent. You will have the same feelings when the stent is put in place as when the balloon was expanded during the procedure.

- The stent, which is mounted on a balloon catheter, is inserted into the artery and placed at the site of the initial blockage.
- When the balloon and stent are positioned, the balloon is inflated. The stent expands and becomes firmly pressed into the inner wall of the artery. One or more stents may be used at the site that was narrowed or blocked.
- X-ray pictures are taken so that the doctor can see the stent in your artery. Additional balloon inflations may be needed to fully expand the stent.
- The balloon catheter is deflated and removed along with the guidewire and guiding catheter.
- The stent will remain in place permanently.

1 Rapamune is a registered trademark of Wyeth Pharmaceuticals

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How Long is the Hospital Stay?

Your hospital stay will be the same as for an angioplasty or non-drug-eluting stent procedure. Many patients are able to go home the day following the procedure. The amount of time that you may stay in the hospital will depend on several factors including any difficulties that you may have experienced during the procedure and how well the puncture site is healing. The amount of time depends on your physician's discharge orders.

What Happens After Your Angioplasty or Stent Procedure?

After your procedure, you will be moved to a special care unit where nurses will be able to monitor your heart rhythm and blood pressure very closely. At this time, the catheter sheath introducer (tube) may be removed and pressure will be applied to the puncture site, either your groin or arm, until the bleeding has stopped. Your puncture site will be watched closely for any signs of bleeding. If your leg was used to insert the catheters, you may be instructed to lie flat for several hours, and you may not be allowed to bend the leg that was used. Should you see any blood or feel warmth at the area of the puncture site, notify your nurse immediately. Your extremity will be monitored for any changes in color, temperature and sensation.

Once you have returned to your room, you may be able to eat and drink and your family may visit depending on your doctor's orders. Eat foods that are light until you are able to sit upright. Drink all of the fluids that are offered, because they will help to flush the x-ray dye through your kidneys and out of your body. Your doctor will advise you when you can get out of bed and walk.

Many patients are able to go home the day following the procedure. The amount of time that you may stay in the hospital will depend on several factors including any difficulties that you may have experienced during the procedure and how well the puncture site is healing. The amount of time depends on your physician's discharge orders.

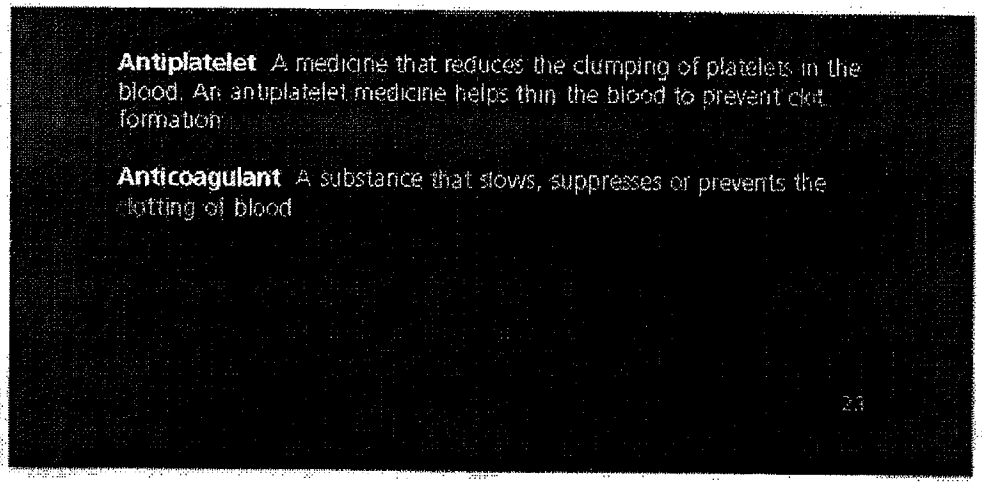
Taking Your Medications is Important

Caution:

- After you leave the hospital you may be instructed to take medications. It is very important that you take your medications exactly as prescribed.
- Be sure not to miss any doses.
- Call your doctor if you feel that you cannot tolerate your medications or develop any side effects such as bleeding, upset stomach, rash, or have any questions.

Depending on which blood thinning medications (also called antiplatelet or anticoagulants) are prescribed, you may need to have follow-up blood tests to monitor the effects of the medicine on your blood. This can be done at your local hospital laboratory or primary care doctor's office and you may have breakfast before having the blood taken.

Your cardiologist may prescribe a number of medications to thin the blood and prevent blood clots from forming and adhering to the surface of the stent. You will be asked to take a small daily dose of aspirin indefinitely. In addition, it is recommended that you take antiplatelet medication for a period of time after stent implantation, which should be a minimum of three months. The antiplatelet medication may be extended to 12 months or longer as determined by your doctor. It is extremely important to follow your medication



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regimen. If you stop taking these medications earlier than instructed by your cardiologist, you increase the chances of having a blood clot, heart attack or even death.

If you plan to have any type of surgery or dental work which may require you to stop taking antiplatelet medications early, you and your cardiologist should discuss whether or not placement of a drug-eluting stent is the right treatment choice for you.

If surgery or dental work which would require you to stop taking antiplatelet medications early is recommended after you've received the stent, you and your doctors should carefully consider the risks and benefits of this surgery or dental work versus the possible risks from early discontinuation of these medications.

If you do require early discontinuation of antiplatelet medications because of significant bleeding, then your cardiologist will be carefully monitoring you for possible complications. Once your condition has stabilized, your cardiologist will possibly put you back on these medications.

Caution. It is Very Important to Follow These Instructions:

1. Follow your medication schedule exactly to avoid possible complications related to stent implantation.
2. Do not stop taking any of the prescribed medications unless you are instructed to do so by the doctor who performed the procedure.
3. Notify your doctor immediately if you experience chest pain (angina) or notice any changes such as more severe or frequent chest discomfort, especially in the first month after a procedure. These symptoms may indicate a re-narrowing in your coronary arteries.
4. Notify your doctor if you experience any side effects of the medications such as nausea, vomiting, and bleeding or rash.
5. Show your identification card (see also "After You Go Home" section) if you report to an emergency room. This card identifies you as a stent implant patient.
6. Keep all appointments for follow-up care including your blood tests.
7. Magnetic Resonance Imaging (MRI) of single or two overlapping CYPHER® Stents has been shown to be safe in MRI units with a magnetic strength of three Tesla or less. Notify your doctor that you have a CYPHER® Stent before you have an MRI medical scan.
8. Notify your cardiologist or family doctor if you are scheduled to see the dentist while on antiplatelet medication. Your physician may prescribe antibiotics to avoid the potential of an infection (see also "After You Go Home" section).

You will be discharged to the care of your cardiologist or family doctor. After returning home, if you experience any pain, discomfort, bleeding of any kind, rash or itching, contact your doctor or the hospital. You should be able to return to your normal activities such as work, sports, and sex very soon. Check with your physician prior to doing anything that is physically strenuous.

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After You Go Home

If you received a stent (uncoated, coated or drug-eluting) you will be given a small wallet-size identification card containing information about the location of your stent or therapy and the date it was performed, along with important doctors' names and telephone numbers. An example of the card is included in the back of this booklet; this card should be kept with you at all times. It is important to alert any doctor that is treating you that you received an uncoated, coated or drug-eluting stent.

If a surgical or dental procedure is recommended while on antiplatelet medication, ask your surgeon or dentist to contact the doctor who performed the stent procedure to discuss the possible risks of stopping your antiplatelet medication early.

Follow-up Visits

You may be instructed to return to see your cardiologist or family doctor. The first visit will usually take place within the first 2-4 weeks after your procedure and every six months for the first year. If you are doing well, the doctor may recommend yearly visits thereafter.

Diet and Lifestyle Changes

To help yourself stay healthy in the future, you are encouraged to make important diet, exercise and lifestyle changes. Some patients may need few modifications while others may need to make many changes. Those patients who are able to reduce the fats and cholesterol in their diets are less likely to redevelop blockages within the stent. A low-fat, low-cholesterol diet can lower the levels of fat in your blood and reduce your risk. Eating healthy foods in the right portions will also help you to maintain or achieve a healthy weight.

In addition to a healthy diet, it is extremely important to avoid smoking. Smoking not only increases the risk of worsening coronary artery disease, but it increases the chance that your PTCA or stent site will close. If you need help with quitting, notify your health care provider.

Other factors that can contribute to heart disease such as stress and lack of exercise should also be evaluated. Steps can be taken to reduce stress in your life and your physician can help you develop a controlled exercise program.

Even after your full recovery, your doctor may want to check your progress from time to time. You can reduce your risk of developing future disease by making healthy lifestyle choices. Be sure to contact your doctor or health care provider if you have any questions or need assistance regarding your lifestyle modifications.

Summary

You have a very important role to play in order to ensure that your procedure will be successful. It is essential that you cooperate with your physician and follow through with your responsibilities as part of the patient/medical team. If you have any questions or concerns, please contact your physician to discuss them. It is important that you get the most benefit from your treatment and join the thousands of people with coronary artery disease who are leading healthy, productive lives.

For more information on patient education, please visit our website: www.CYPHERUSA.com.

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Glossary

Angina (Pectoris) - Chest discomfort, pain, tightness or pressure. May also have associated pain in neck, jaw, back or arm. May include profuse sweating, nausea, or shortness of breath. Angina may be a single symptom or a combination of these symptoms.

Angioplasty - A balloon procedure to open an obstruction or narrowing of a blood vessel. Also known as percutaneous transluminal coronary angioplasty (PTCA).

Anticoagulant - A substance that slows, suppresses or prevents the clotting of blood.

Antiplatelet - A medicine that reduces the clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

Atherosclerosis - A disease process in which fatty substances (plaque), such as cholesterol, are deposited on the inner lining of blood vessels.

Brachytherapy - *See Intravascular Brachytherapy.*

Coronary Artery Bypass Graft (CABG) Surgery - An operation in which a piece of vein or artery is used to bypass a blockage in a coronary artery; performed to prevent myocardial infarction and relieve angina pectoris.

CAD - Coronary Artery Disease.

Cardiac - Relating to the heart.

Cardiac Catheterization - *See Coronary Angiogram.*

CAT Scanning - *See Computered Tomography Scanning.*

Catheter - A tube used for gaining access to one of the body's cavities or blood vessels. In angioplasty, a catheter provides access to the heart's arteries.

Catheterization - A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.

Cholesterol - A substance that circulates in the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fats.

Computered Tomography Scanning - A technique for producing cross-sectional images of the body in which x-rays are passed through the body at different angles and analyzed by a computer; also called CT scanning or CAT scanning.

Coronary - Related to the arteries that supply blood to the heart.

Coronary Angiogram - A test used to diagnose CAD using the catheterization procedure. Contrast dye is injected into the coronary arteries via a catheter, and this allows the doctor to see, on a x-ray screen, the exact site where the artery is narrowed or blocked.

Coronary Arteries - The coronary arteries are special blood vessels which supply the heart with necessary oxygen and nutrients. The heart does not function properly without enough oxygen.

Coronary Artery Disease - Atherosclerosis of the coronary arteries.

CT Scanning - *See Computer Tomography Scanning.*

Diabetes - A disease affecting one's metabolism of glucose (sugar) which causes changes in blood vessels. These changes may aid in the development of coronary artery disease.

EKG - Electrocardiogram. A test that measures and shows the electrical activity of the heart muscle.

Exercise Electrocardiogram - *See Stress Test.*

Fluoroscope - Equipment used in a cardiac catheterization procedure which captures a "motion picture" x-ray image of the heart and coronary arteries.

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In-stent Restenosis - A re-narrowing or blockage of an artery within a stent.

Intravascular Brachytherapy - The administration of a therapeutic dose of radiation from within a vessel to a specific area of vascular disease to prevent the reoccurrence of an obstruction or narrowing.

Ischemia - Lack of or insufficient oxygen to the tissue, in this case, to the heart muscle. Ischemia is a reversible condition if normal blood flow is restored.

Left Ventricle - The largest chamber of the heart which is responsible for pumping blood throughout the body.

Lesion - A blockage in a blood vessel. It is also known as a plaque or stenosis.

MRI - Magnetic Resonance Imaging. A diagnostic study similar to a CT or CAT scan which creates an image using electromagnetic waves instead of x-ray.

Myocardial Infarction - Commonly called a "heart attack." Involves irreversible damage to heart tissue/muscle. Insufficient oxygen reaching the heart muscle via the coronary arteries may cause angina, heart attack (myocardial infarction), or even death to the affected area of the heart.

Percutaneous - Performed through a small opening in the skin.

Percutaneous Transluminal Coronary Angioplasty - *See Angioplasty.*

Plaque - The accumulated material that causes a blockage in a blood vessel. Also known as a lesion or stenosis.

Platelets - Blood cells that are involved in the formation of a clot.

PTCA - Percutaneous Transluminal Coronary Angioplasty. *See Angioplasty.*

Restenosis - A re-narrowing or blockage of an artery at the same site where angioplasty was previously done.

Stenosis - A narrowing of any canal, especially one of the cardiac vessels.

Stent - An expandable, slotted metal tube, inserted into a vessel. A stent acts as a scaffold to provide structural support for a vessel.

Stress Test - A test that measures electrical changes in the patient's heart (EKG) while the patient is doing controlled exercise. The stress test can show if there has been damage to the heart or if there is decreased blood flow to areas of the heart.

Tesla - A unit measure of magnetic strength.

Thrombosis/Late Thrombosis/Very Late Thrombosis - A blockage caused by clumping of cells. Late Thrombosis occurs after 30 days of stent implantation. Very late thrombosis occurs after one year of stent implantation.

Transluminal - Through the inside opening of an artery.

Triglycerides - Substances in the blood that are a component of the "bad" type of cholesterol.

Vessel - Any channel for carrying a fluid, such as an artery or vein.

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Notes